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Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for all designations
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations

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- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



WO 03/039562 A1

Atty. Docket No.: 2664H-000110/US
Serial No.: 09/683,003
Applicant: Yu, et al.
Reference 6 of 10

(54) Title: COMPOSITION AND METHOD

(57) Abstract: A composition which comprises about 0.1 to about 4.5 mg selenium/kg of diet on a dry matter basis

COMPOSITION AND METHODBACKGROUND OF THE INVENTION

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Selenium is well known as an essential component of a mammal's diet. Many functions have been associated with it. These include growth, reproduction, antioxidant, endocrine function, immune function, normal hair growth, muscle, and heart function. Selenium has been used in hair shampoos as an antidandruff agent, see USP 5,798, 121
10 and 5,702,690 as the disulphide and sulphide. Topical application of selenium has been implicated in hair growth, see USP 5,629,002 wherein inorganic selenium compounds together with thiocyanic compounds are disclosed as improving quality and stimulating the growth of hair. At column 1, lines 28-44 of 002, various materials including selenium, are disclosed as:

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"can display a more or less stimulating influence on the growth of the hair. However, the effects achieved thereby, as a rule, are not significant and not reproducible in practice."

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We have now found a range of dietary selenium that stimulates hair growth of dogs and cats receiving a properly nutritious diet. Quantitative measures show hair growth rate is statistically greater within this range. Below and above the range, hair growth is slowed. Providing a steady positive growth rate for hair can be desirable for esthetic benefits. Enhancing hair growth with selenium supplementation can benefit the management of disorders of the hair follicles and/or hair coat by preventing or treating
25 poor hair growth or alopecia related to disease, reproductive cycle, seasonal changes or direct hair removal (e.g., shaving or clipping).

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SUMMARY OF THE INVENTION

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In accordance with the invention, there is a composition which comprises about 0.1 to about 4.5 mg selenium/kg of diet on a dry matter basis, the diet providing nutritional sustenance. Generally, hair growth is slowed when dietary selenium concentration is below about 0.1 mg selenium/kg diet and above about 4.5 mg

selenium/kg diet on a dry matter basis. Thus, the range between 0.1 and 4.5 mg selenium/kg diet maximizes hair growth.

A further aspect of the invention is a method for controlling the rate of hair growth in a dog or cat which comprises feeding the dog or cat a hair growth rate controlling amount of selenium of from about 0.1 to about 4.5 mg per kg diet on dry matter basis, the diet providing nutritional sustenance. Otherwise, the selenium can be fed the dog or cat as a supplement to the regular diet as long as the appropriate levels of selenium are maintained.

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DETAILED DESCRIPTION OF THE INVENTION

Selenium can be administered orally to the dog or cat in any form as long as it is absorbed by the animals. Examples of such forms of selenium include salts such as selenites and selenates, for example, sodium selenite, and sodium selenate; acids such as selenious and selenic acid; organic compounds containing selenium such as selenomethionine, selenocysteine, selenohomocystine, selenotaurine; and selenium containing food or ingredients such as meat, fish, and the like.

The quantity of selenium as disclosed in this specification is measured as the quantity of selenium per se. For example, if selenium is administered as selenomethionine, it is the actual quantity of selenium that is in the selenomethionine that is intended as the quantity disclosed. The minimum quantity of selenium that brings about the controlled rate of hair growth in cats and dogs is about 0.1 mg as measured per kg diet on dry matter basis. The maximum quantity is a controlling hair growth rate but non-toxic quantity of selenium. Generally, this is no more than about 4.5 mg, desirably no more than about 2 mg per kg diet on dry matter basis. A desirable minimum is about 0.5 mg per kg diet on dry matter basis. As stated previously, it has now been found that the control of hair growth rate through usage of selenium can result in a pronounced statistically significant hair growth acceleration depending upon the quantity of selenium employed. Hair growth rate increases and reaches its maximum when dietary selenium concentration is above 0.1 mg selenium/kg diet and hair growth is slowed when dietary selenium concentration is higher than about 4.5 mg selenium/kg. Selenium can be

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administered to the dog or cat in diet or through specific supplements to be fed to the animal.

5 Animals that benefit from increased hair growth rate are dogs, cats, ferrets, sheep, and other mammals.

In addition to optimizing growth of hair coat for esthetic benefits, enhancing hair growth with selenium supplementation can benefit the management of disorders of the skin, hair follicle and/or hair coat by preventing or treating poor hair growth or alopecia
10 related to disease, reproductive cycle, seasonal changes or direct hair removal (e.g., shaving or clipping).

Below is an example of the invention showing the benefit and effect of using selenium.

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Example 1

Adult beagles of both male and females are used. They are between 1.2 and 3.7 years of age at the start of the experiment.

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Study Design: Thirty-six adult dogs are divided into six groups of six dogs in each group based on their age, gender and body condition score so that the averages of those three criteria are similar among groups. All dogs are given the basal diet for three weeks (pre-treatment period) before they are allocated to one of the experimental diets. The third
25 week of the pre-treatment period is considered as week 0 of the study. Hair growth is measured in weeks 0, 11 and 22 of the study using the method described below. Dogs are fed with the experimental diets for 24 weeks.

A torula yeast basal diet is used. The basal diet is nutritionally complete and
30 balanced for an adult dog except for selenium. Different amounts of selenium (as selenomethionine) are added into the basal diet to form six experimental diets which contain 0, 0.05, 0.1, 0.5, 1 or 5 mg selenium/kg diet dry matter, respectively. Selenium concentrations in the experimental diets are confirmed by chemical analyses. The analyzed dietary selenium concentrations were 0.034, 0.085, 0.123, 0.527, 1.025 and
35 5.045 mg/kg dry matter, respectively.

Hair Growth Measurement: Hairs in an area of 2" x 2" on the left side of the body above the hind leg and about 3 cm away from the spinal are clipped with an electronic clipper (Oster Pro™ Model 78400-01A, blade size: 40.1mm, Oster Elite™). The hair is cut as close to the skin as possible. A tattoo dot of about 1 mm in diameter is made in the center of the clipped area using a tattoo marker (Spaulding Special Electric Tattoo Marker, Model SSEMK). Hair growth is measured by taking photographs from the same clipped area twice using the tattoo dot as a marker. The first photograph is taken right after the clipping and the second photograph four days later. A Polaroid close-up camera (CU-5) and Polaroid 665 films are used to take photographs. A glass slide is attached to the front frame of the camera to press hairs to the skin to minimize errors caused by the angle formed between standing hair and the skin. The image is magnified three times by the camera. Same exposure conditions are used for all dogs in the study. On each day of photograph shooting, a photograph is also taken of a ruler with clear markers under the same conditions and serves as a reference. After exposure, both prints and negatives of the films are treated according to the use directions. The negative films provide sharp and clear images of hairs and are used for hair growth measurement. The negative films are scanned (EPSON Expression 836XL) into a computer. Afterwards, the length of primary hairs in the film is measured using an image analyzing software (BioScan Optimas). The difference of the average hair lengths between the first and the second photographs from the same dog is the hair growth during the four-day period.

Results: There is no difference in hair growth among groups in week 0 (Table 1). However, dogs given diets containing 0.1, 0.5 or 1 mg selenium/kg diet have a significantly ($p<0.05$) higher rate of hair growth than dogs receiving diets with 0, 0.05 or 25 5 mg selenium/kg diet in week 11 and 22 of the study.

Table 1
Hair growth of Beagles fed diets with various levels of selenium

		<u>Hair growth (mm/day)</u>		
		<u>Week 0</u>	<u>Week 11</u>	<u>Week 22</u>
	0.034	0.21	0.12	0.12
	0.085	0.18	0.15	0.11
	0.123	0.13	0.26	0.20
10	0.527	0.15	0.22	0.23
	1.025	0.18	0.26	0.20
	5.045	0.20	0.14	0.13

No apparent clinical signs of selenium deficiency or toxicity are observed in the dogs
15 during the study period. Average food intake and body weights are not affected by the dietary treatments. Blood CBC and chemistry measurements as well as serum total thyroxine and 3, 5, 3' – triiodothyronine are within the normal ranges. These results demonstrate that dietary selenium concentrations from 0.1 to about 4.5 mg selenium/kg diet maximize hair growth of dogs, with preferred levels between about 0.1 and about 2
20 mg selenium/kg diet and most preferred at about 0.1 to about 1 mg selenium/kg diet dry matter.

CLAIMS

1. A composition which comprises about 0.1 to about 4.5 mg selenium/kg of dog or cat diet on a dry matter basis, the diet providing nutritional sustenance for an animal.
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2. A method for controlling the rate of hair growth in a dog or cat which comprises feeding the dog or cat a hair growth rate controlling amount of selenium of from about 0.1 to about 4.5 selenium mg /kg of diet on a dry matter basis.
- 10 3. A method for preventing or treating poor hair growth or alopecia in animals in need of said treatment, related to disease, reproduction cycle, seasonal changes or direct hair removal which comprises feeding the animal a hair growth rate controlling amount of selenium of from about 0.1 to about 4.5 mg/kg of diet on a dry matter basis.
15
4. The method in accordance with claim 3 wherein the animal is a dog, cat, or sheep.
5. The method in accordance with claim 4 wherein the animal is a dog or cat.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/35546

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K33/04 A23K1/175 A23K1/18

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K A23K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, PAJ, FSTA, BIOSIS, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 238 708 B1 (HAYEK MICHAEL GRIFFIN ET AL) 29 May 2001 (2001-05-29) table 8 ---	1
X	US 6 156 355 A (BENNETT JEFFREY P ET AL) 5 December 2000 (2000-12-05) column 10, paragraph 5 example 4 ---	1 -/-

 Further documents are listed in the continuation of box C. Patent family members are listed in annex.

* Special categories of cited documents :

- *'A' document defining the general state of the art which is not considered to be of particular relevance
- *'E' earlier document but published on or after the international filing date
- *'L' document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *'O' document referring to an oral disclosure, use, exhibition or other means
- *'P' document published prior to the international filing date but later than the priority date claimed

*'T' later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

*'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

*'Y' document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

*'&' document member of the same patent family

Date of the actual completion of the international search

11 February 2003

Date of mailing of the international search report

04/03/2003

Name and mailing address of the ISA

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/35546

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	LEE, J., MASTERS, D. G., WHITE, C. L., GRACE, N. D., AND JUDSON, G. J.: "Current issues in trace element nutrition of grazing livestock in Australia and New Zealand" AUSTRALIAN JOURNAL OF AGRICULTURAL RESEARCH, vol. 50, no. 8, 1999, pages 1341-1364, XP008013354 MELBOURNE, AU page 1344, column 2, paragraph 4 -page 1345, column 1, paragraph 2 ---	1-5
X	US 5 629 002 A (KOCH STEFAN ET AL) 13 May 1997 (1997-05-13) cited in the application column 6, paragraphs 1-3 claim 1; example 9 ---	1-5
X	DATABASE WPI Section Ch, Week 199727 Derwent Publications Ltd., London, GB; Class D13, AN 1997-289978 XP002230564 & CN 1 103 558 A (MEAT PIGEON COMPREHENSIVE TECHNOLOGY DEV), 14 June 1995 (1995-06-14) abstract ---	1-5
A	EP 0 583 026 A (SREDNI BENJAMIN ;ALBECK MICHAEL (IL)) 16 February 1994 (1994-02-16) claim 1 ---	1-5
A	GB 1 444 024 A (PASSWATER A) 28 July 1976 (1976-07-28) claim 1 ---	1-5

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 02/35546

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
US 6238708	B1	29-05-2001	AU BR CA CN EP HU JP NO TR WO US	3371900 A 0008409 A 2360495 A1 1340996 T 1173068 A1 0105193 A2 2002536985 A 20014076 A 200102474 T2 0049891 A1 2001018067 A1		14-09-2000 05-02-2002 31-08-2000 20-03-2002 23-01-2002 29-05-2002 05-11-2002 22-08-2001 21-01-2002 31-08-2000 30-08-2001
US 6156355	A	05-12-2000		NONE		
US 5629002	A	13-05-1997	DE WO JP	4100975 A1 9212699 A1 6506913 T		16-07-1992 06-08-1992 04-08-1994
CN 1103558	A	14-06-1995		NONE		
EP 0583026	A	16-02-1994	US AT DE DE DK EP ES GR	5262149 A 142875 T 69304843 D1 69304843 T2 583026 T3 0583026 A1 2093357 T3 3021813 T3		16-11-1993 15-10-1996 24-10-1996 10-04-1997 24-02-1997 16-02-1994 16-12-1996 28-02-1997
GB 1444024	A	28-07-1976		NONE		

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Rule 71.1)

Date of mailing
(day/month/year)

06.02.2004

Applicant's or agent's file reference 6601-00	IMPORTANT NOTIFICATION	
International application No. PCT/US 02/35546	International filing date (day/month/year) 06.11.2002	Priority date (day/month/year) 07.11.2001
Applicant HILL'S PET NUTRITION, INC.		

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



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PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 6601-00	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US 02/35546	International filing date (day/month/year) 06.11.2002	Priority date (day/month/year) 07.11.2001	
International Patent Classification (IPC) or both national classification and IPC A61K33/04			
Applicant HILL'S PET NUTRITION, INC.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the opinion II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application 			

Date of submission of the demand 05.06.2003	Date of completion of this report 06.02.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Rooney, K Telephone No. +31 70 340-3931



INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US 02/35546

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-5 as originally filed

Claims, Numbers

1-5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US 02/35546

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	2,5
	No:	Claims	1,3,4
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-5
Industrial applicability (IA)	Yes:	Claims	1-5
	No:	Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US02/35546

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

- D1: US-B1-6238708
- D2: US-A-6156355
- D3: Australian Journal Of Agricultural Research (1999), 50(8), 1341-1364
- D4: US-A-5629002
- D5: Derwent WPI; AN: 1997-289978(CN(A) 1103558)

2. The present application does not meet the requirements of Article 33 (2) PCT because the subject-matter of claim 1,3 and 4 is not new.

The document D1 discloses a composition which comprises 0.27 mg selenium per Kg dry matter of the composition (see D1; table 8). The disclosure of D1 removes novelty from the subject-matter of claim 1.

The document D2 discloses a composition which comprises at least 0.4 mg selenium per Kg dry matter of the composition (see D1; example 4). The disclosure of D2 also removes novelty from the subject-matter of claim 1.

The document D3 discloses the dietary requirements of sheep as being 0.1-0.3 mg selenium per Kg of dry matter in the diet. The effect of the selenium in the diet is to control wool growth (see D3; page 1344, column 2 - page 1345, column 1). The disclosure of D3 removes novelty from the subject matter of claims 1, 3 and 4.

The document D4 discloses a composition which consists of 0.1 mg of selenium per litre (1 Kg) of composition. The effect of the composition is to cause hair growth in the treated animal when given orally (see D4; example 9). The disclosure of D4 removes novelty from the subject-matter of claims 1 and 3.

The document D5 discloses compositions containing 0.5 - 350 mg selenium per Kg of diet. The effect of the composition is to control alopecia (see D5; abstract). The disclosure of D5 removes novelty from the subject-matter of claims 1 and 3.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US02/35546

3. Furthermore, the present application does not meet the requirements of Article 33 (3) PCT because the subject-matter of claims 2 and 5 does not involve an inventive step.

The document D3 describes the effect of selenium in the diet at 0.1-0.3 mg per Kg of diet on the growth of hair in sheep. Given the teaching of D3, the skilled person would consider it a normal design option to include selenium in the diet of a cat or dog in order to solve the problem of controlling the rate of hair growth.

Furthermore, the document D5 discloses compositions containing 0.5 - 350 mg selenium per Kg diet. The compositions are used for the treatment of alopecia (see D5; abstract). The use of selenium in D5 provides the same advantages as in the present application. The skilled person would therefore regard it as a normal option to include this feature in a composition for cats or dogs in order to solve the problem posed.